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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,222	12/20/2001	Ranjani V. Parthasarathy	57314US002	9052

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary

Application No. 10/027,222		Applicant(s) PARTHASARATHY ET AL.	
Examiner Dwayne K Handy		Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42, 44, 45 and 53-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 39-42, 44, 45 and 53-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner. .
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8, 10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the Restriction requirement in Paper No. 9 is acknowledged. The traversal is on the ground(s) that examining the claims of Group I, would not place an undue burden on the Examiner. This is not found persuasive because the issue is not the burden on the Examiner, but whether or not the apparatus as claimed can be used to practice another and materially different process. As stated in the previous action, the apparatus as claimed can be used for performing chemical reactions in array form.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or invention, there being no allowable generic or linking claim.

Claim Objections

2. Claims 55-63 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claims 55-63 applicant is placing a limitation on the material to be tested in the device – the biological sample mixture - not the device itself. This would also be an intended use of the device and is given no patentable weight during examination.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 39-42, 44, 45 and 54-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of copending Application No. 10/417,609.

Claims 39-42 and 54-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of copending Application No. 10/027,226 in view of Nelson (6,344,326).

These rejections are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. **These rejections were previously made in the previous office action, paper no. 7. Applicant has stated that an appropriate response will be provided upon the determination of otherwise allowable subject matter.**

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 39-41, 44, 45 and 53-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (6,344,326) in view of Gjerde et al. (6,265,168). The teachings of Nelson were cited in the previous action (paragraph 11). Nelson teaches every element of claims 39-41, 44, 45 and 53-65 except for the specific exchange material being an anion exchange material partially coated with a negatively charged polymer. This teaching was provided by Gjerde (6,265,168) and was also cited in the previous action (paragraph 16). The Examiner now applies the previous rejections to the amended and newly added claims. Please see Response to Arguments below.
8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (6,344,326) and Gjerde et al. (6,265,168) as applied above, and further in view of Mian (6,319,469). Nelson and Gjerde teach every element of claim 42 except for the array arranged radially on the device. Mian teaches a microfluidic device with a plurality of arrays arranged radially on the platform. The arrays are arranged radially in order to take advantage of centripetal force to motivate fluid movement through the channels of the array (Abstract, Figure 1C, column 3 lines 36-57 and columns 9-11). It would have been obvious to one of ordinary skill in the art to combine the radial arrays of Mian with the teachings of Gjerde. The use of Mian's arrays would allow for the use of centripetal force to drive fluids through the separation media.

Response to Arguments

9. Applicant's arguments with respect to the rejection involving the reference "Swedberg" have been fully considered and are persuasive. This rejection has been withdrawn. The Examiner also removed the rejection of claim 42 involving the reference Nelson. Nelson does not teach arrays that are arranged in a radial fashion.
10. Applicant's arguments filed with respect to the remaining/new rejections based on the references Nelson and Gjerde have been fully considered but they, however, are not persuasive. Applicant has argued the following in traversing the rejections involving Nelson: (1) Nelson is not "operable" to remove small negatively charged materials; and (2) Nelson nor Gjerde does not teach an anion exchange material partially coated with a negative polymer. The Examiner disagrees on both counts. As to the first line of argument, this is an intended use of the device. No structural limitation is provided by the phrase "operable to remove small negatively charged molecules...." Furthermore, even if this phrase did provide a further limitation of the device, the combined teachings of Nelson and Gjerde would be "operable to remove negatively charged molecules" simply by providing the anion exchange material. In making the second argument, applicant has highlighted a passage from Gjerde which notes the formation of a neutral surface in the exchange media. This is a spurious argument. Applicant has not specified in the claim that the **surface** must be negative. Applicant has only specified that the anion exchange material be coated with a **negatively charged polymer**. This is, in fact, what Gjerde cites – in the same passage cited by applicant ("polymers having

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a negative charge may also be used...."). Applicant has used open claim language (comprising) and therefore other features may be present in the cited reference. This would include positively charged groups which may be present to provide the neutral charge.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al. (6,197,595) and Sheppard, Jr. et al. (6,143,247) show microfluidic devices which may also be used in nucleic acid separation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.



ARLEN SODERQUIST
PRIMARY EXAMINER

Dkh
December 29, 2003